106TH CONGRESS
2D SESSION

S. 2738

To amend the Public Health Service Act to reduce medical mistakes and medication-related errors.

IN THE SENATE OF THE UNITED STATES

JUNE 15, 2000

Mr. JEFFORDS (for himself, Mr. FRIST, and Mr. ENZI) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Public Health Service Act to reduce medical mistakes and medication-related errors.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Patient Safety and Errors Reduction Act''.

SEC. 2. PURPOSES.

It is the purpose of this Act to—

(1) promote the identification, evaluation, and reporting of medical errors;

(2) raise standards and expectations for improvements in patient safety;

(3) reduce deaths, serious injuries, and other medical errors through the implementation of safe practices at the delivery level;

(4) develop error reduction systems with legal protections to support the collection of information under such systems;

(5) extend existing confidentiality and peer review protections to the reports relating to medical errors that are reported under such systems that are developed for safety and quality improvement purposes; and

(6) provide for the establishment of systems of information collection, analysis, and dissemination to enhance the knowledge base concerning patient safety.

SEC. 3. AMENDMENT TO PUBLIC HEALTH SERVICE ACT.

Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) is amended—

(1) by redesignating part C as part D;

(2) by redesignating sections 921 through 928, as sections 931 through 938, respectively;

(3) in section 938(1) (as so redesignated), by striking ''921'' and inserting ''931''; and

(4) by inserting after part B the following:

"PART C—REDUCING ERRORS IN HEALTH CARE

"SEC. 921. DEFINITIONS.

''In this part:

''(1) ADVERSE EVENT.—The term 'adverse event' means, with respect to the patient of a provider of services, an untoward incident, therapeutic misadventure, or iatrogenic injury directly associated with the provision of health care items and services by a health care provider or provider of services.

''(2) CENTER.—The term 'Center' means the Center for Quality Improvement and Patient Safety established under section 922(b).

''(3) CLOSE CALL.—The term 'close call' means, with respect to the patient of a provider of services, any event or situation that—

''(A) but for chance or a timely intervention, could have resulted in an accident, injury, or illness; and

''(B) is directly associated with the provision of health care items and services by a provider of services.

''(4) EXPERT ORGANIZATION.—The term 'expert organization' means a third party acting on behalf of, or in conjunction with, a provider of services

to collect information about, or evaluate, a medical event.

''(5) HEALTH CARE OVERSIGHT AGENCY.—The term 'health care oversight agency' means an agency, entity, or person, including the employees and agents thereof, that performs or oversees the performance of any activities necessary to ensure the safety of the health care system.

''(6) HEALTH CARE PROVIDER.—The term 'health care provider' means—

''(A) any provider of services (as defined in section 1861(u) of the Social Security Act); and

''(B) any person furnishing any medical or other health care services as defined in section 1861(s)(1) and (2) of such Act through, or under the authority of, a provider of services described in subparagraph (A).

''(7) PROVIDER OF SERVICES.—The term 'provider of services' means a hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, renal dialysis facility, ambulatory surgical center, or hospice program, and any other entity specified in regulations promulgated by the Secretary.

''(8) PUBLIC HEALTH AUTHORITY.—The term 'public health authority' means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, and an Indian tribe that is responsible for public health matters as part of its official mandate.

''(9) MEDICAL EVENT.—The term 'medical event' means, with respect to the patient of a provider of services, any sentinel event, adverse event, or close call.

''(10) MEDICAL EVENT ANALYSIS ENTITY.—The term 'medical event analysis entity' means an entity certified under section 923(a).

''(11) ROOT CAUSE ANALYSIS.—

''(A) IN GENERAL.—The term 'root cause analysis' means a process for identifying the basic or contributing causal factors that underlie variation in performance associated with adverse events or close calls that—

''(i) has the characteristics described in subparagraph (B);

''(ii) includes participation by the leadership of the organization and individuals most closely involved in the processes and systems under review;

''(iii) is internally consistent; and

''(iv) includes the consideration of relevant literature.

''(B) CHARACTERISTICS.—The characteristics described in this subparagraph include the following:

''(i) The analysis is interdisciplinary in nature and involves those individuals who are responsible for administering the reporting systems.

''(ii) The analysis focuses primarily on systems and processes rather than individual performance.

''(iii) The analysis involves a thorough review of all aspects of the process and all contributing factors involved.

''(iv) The analysis identifies changes that could be made in systems and processes, through either redesign or development of new processes or systems, that would improve performance and reduce the risk of adverse events or close calls.

''(12) SENTINEL EVENT.—The term 'sentinel event' means, with respect to the patient of a provider of services, an unexpected occurrence that—

''(A) involves death or serious physical or psychological injury (including loss of a limb); and

''(B) is directly associated with the provision of health care items and services by a provider.

"SEC. 922. RESEARCH TO IMPROVE THE QUALITY AND SAFETY OF PATIENT CARE.

''(a) IN GENERAL.—To improve the quality and safety of patient care, the Director shall—

''(1) conduct and support research, evaluations and training, support demonstration projects, provide technical assistance, and develop and support partnerships that will identify and determine the causes of medical errors and other threats to the quality and safety of patient care;

''(2) develop or identify and evaluate interventions and strategies for preventing or reducing medical errors and threats to the quality and safety of patient care;

''(3) develop, in conjunction with experts in the field, reporting requirements to provide consistency throughout the errors reporting system;

''(4) develop approaches for the clinical management of complications from medical errors; and

''(5) establish mechanisms for the rapid dissemination of interventions and strategies developed under this section for which there is scientific evidence of effectiveness.

''(b) CENTER FOR QUALITY IMPROVEMENT AND PATIENT SAFETY.—

''(1) ESTABLISHMENT.—The Director shall establish a center to be known as the Center for Quality Improvement and Patient Safety to assist the Director in carrying out the requirements of subsection (a).

''(2) MISSION.—The Center shall—

''(A) provide national leadership for research and other initiatives to improve the quality and safety of patient care;

''(B) develop public-private sector partnerships to improve the quality and safety of patient care; and

''(C) serve as a national resource for research and learning from medical errors.

''(3) DUTIES.—

''(A) IN GENERAL.—In carrying out this section, the Director, acting through the Center, shall consult and develop partnerships, as appropriate, with all segments of the health

care industry, including health care practitioners and patients, those who manage health care facilities, systems and plans, peer review organizations, health care purchasers and policymakers, and other users of health care research.

''(B) REQUIRED DUTIES.—In addition to the broad responsibilities that the Director may assign to the Center for research and related activities that are designed to improve the quality of health care, the Director shall ensure that the Center—

''(i) builds scientific knowledge and understanding of the causes of medical errors in all health care settings and identifies or develops and validates effective interventions and strategies to reduce errors and improve the safety and quality of patient care;

''(ii) promotes public and private sector research on patient safety by—

''(I) developing a national patient safety research agenda;

''(II) identifying promising opportunities for preventing or reducing medical errors; and

''(III) tracking the progress made in addressing the highest priority research questions with respect to patient safety;

''(iii) facilitates the development of voluntary national patient safety goals by convening all segments of the health care industry and tracks the progress made in meeting those goals;

''(iv) develops national patient safety data for inclusion in the annual report on the quality of health care required under section 913(b)(2);

''(v) strengthens the ability of the United States to learn from medical errors by—

''(I) developing the necessary tools and advancing the scientific techniques for analysis of errors;

''(II) providing technical assistance as appropriate to reporting systems; and

''(III) entering into contracts to receive and analyze aggregate data from public and private sector reporting systems;

''(vi) supporting dissemination and communication activities to improve patient safety, including the development of tools and methods for educating consumers about patient safety; and

''(vii) undertaking other activities that the Director determines are necessary to enable the Center to fulfill its mission.

''(C) LIMITATION.—Aggregate data gathered for the purposes described in this section shall not include specific patient, health care provider, or provider of service identifiers.

''(c) LEARNING FROM MEDICAL ERRORS.—

''(1) IN GENERAL.—To enhance the ability of the health care community in the United States to learn from medical errors and close calls, the Director shall—

''(A) carry out activities to increase scientific knowledge and understanding regarding medical error reporting systems;

"(B) carry out activities to advance the scientific knowledge regarding the tools and techniques for analyzing medical errors and determining their root causes;

"(C) carry out activities in partnership with experts in the field to increase the capacity of the health care community in the United States to analyze patient safety data;

"(D) develop a confidential national safety database of medical errors reports;

"(E) conduct and support research, using the database developed under subparagraph (D), into the causes and potential interventions to decrease the incidence of medical errors and close calls; and

"(F) ensure that information contained in the national database developed under subparagraph (D) does not include specific patient, health care provider, or provider of service identifiers.

"(2) NATIONAL PATIENT SAFETY DATABASE.—The Director shall, in accordance with paragraph (1)(D), establish a confidential national safety database (to be known as the National Patient Safety Database) of reports of medical errors and close

calls that can be used only for research to improve the quality and safety of patient care. In developing and managing the National Patient Safety Database, the Director shall—

''(A) ensure that the database can only be used for its intended purpose;

''(B) ensure that the database is as comprehensive as possible by aggregating data from Federal, State, and private sector patient safety reporting systems;

''(C) conduct and support research on the most common medical errors and close calls, their causes, and potential interventions to reduce medical errors and improve the quality and safety of patient care;

''(D) report findings made by the Director, based on the data in the database, to clinicians, individuals who manage health care facilities, systems, and plans, patients, and other individuals who can act appropriately to improve patient safety; and

''(E) develop a rapid response capacity to provide alerts when specific health care practices pose an imminent threat to patients or health care workers.

''(3) CONFIDENTIALITY AND PEER REVIEW PROTECTIONS.—Notwithstanding any other provision of law any information (including any data, reports, records, memoranda, analyses, statements, and other communications) developed by or on behalf of a health care provider or provider of services with respect to a medical event, that is contained in the National Patient Safety Database shall be confidential in accordance with section 925.

''(4) PATIENT SAFETY REPORTING SYSTEMS.—The Director shall identify public and private sector patient safety reporting systems and build scientific knowledge and understanding regarding the most effective—

''(A) components of patient safety reporting systems;

''(B) incentives intended to increase the rate of error reporting;

''(C) approaches for undertaking root cause analyses;

''(D) ways to provide feedback to those filing error reports;

''(E) techniques and tools for collecting, integrating, and analyzing patient safety data; and

''(F) ways to provide meaningful information to patients, consumers, and purchasers that will enhance their understanding of patient safety issues.

''(5) TRAINING.—The Director shall support training initiatives to build the capacity of the health care community in the United States to analyze patient safety data and to act on that data to improve patient safety.

''(d) EVALUATION.—The Director shall recommend strategies for measuring and evaluating the national progress made in implementing safe practices and standards identified by the Center through the research and analysis required under subsection (b) and through the voluntary reporting system established under subsection (c).

''(e) IMPLEMENTATION.—In implementing strategies to carry out the functions described in subsections (b), (c), and (d), the Director may contract with public or private entities on a national or local level with appropriate expertise.

''SEC. 923. MEDICAL EVENT ANALYSIS ENTITIES.

''(a) IN GENERAL.—The Director, based on information collected under section 922(c), shall provide for the certification of entities to collect and analyze information

on medical errors, and to collaborate with health care providers or providers of services in collecting information about, or evaluating, certain medical events.

''(b) COMPATIBILITY OF COLLECTED DATA.—To ensure that data reported to the National Patient Safety Database under section 922(c)(2) concerning medical errors and close calls are comparable and useful on an analytic basis, the Director shall require that the entities described in subsection (c) follow the recommendations regarding a common set of core measures for reporting that are developed by the National Forum for Health Care Quality Measurement and Reporting, or other voluntary private standard-setting organization that is designated by the Director taking into account existing measurement systems and in conjunction with experts in the field.

''(c) DUTIES OF CERTIFIED ENTITIES.—

''(1) IN GENERAL.—An entity that is certified under subsection (a) shall collect and analyze information, consistent with the requirement of subsection (b), provided to the entity under section 924(a)(5) to improve patient safety.

''(2) INFORMATION TO BE REPORTED TO THE ENTITY.—A medical event analysis entity shall, on a periodic basis and in a format that is specified by

the Director, submit to the Director a report that contains—

"(A) a description of the medical events that were reported to the entity during the period covered under the report;

"(B) a description of any corrective action taken by providers of services with respect to such medical events or any other measures that are necessary to prevent similar events from occurring in the future; and

"(C) a description of the systemic changes that entities have identified, through an analysis of the medical events included in the report, as being needed to improve patient safety.

"(3) COLLABORATION.—A medical event analysis entity that is collaborating with a health care provider or provider of services to address close calls and adverse events may, at the request of the health care provider or provider of services—

"(A) provide expertise in the development of root cause analyses and corrective action plan relating to such close calls and adverse events; or

''(B) collaborate with such provider of services to identify on-going risk reduction activities that may enhance patient safety.

''(d) CONFIDENTIALITY AND PEER REVIEW PROTECTIONS.—Notwithstanding any other provision of law, any information (including any data, reports, records, memoranda, analyses, statements, and other communications) collected by a medical event analysis entity or developed by or on behalf of such an entity under this part shall be confidential in accordance with section 925.

''(e) TERMINATION AND RENEWAL.—

''(1) IN GENERAL.—The certification of an entity under this section shall terminate on the date that is 3 years after the date on which such certification was provided. Such certification may be renewed at the discretion of the Director.

''(2) NONCOMPLIANCE.—The Director may terminate the certification of a medical event analysis entity if the Director determines that such entity has failed to comply with this section.

''(f) IMPLEMENTATION.—In implementing strategies to carry out the functions described in subsection (c), the Director may contract with public or private entities on a national or local level with appropriate expertise.

"SEC. 924. PROVIDER OF SERVICES SYSTEMS FOR REPORTING MEDICAL EVENTS.

''(a) INTERNAL MEDICAL EVENT REPORTING SYSTEMS.—Each provider of services that elects to participate in a medical error reporting system under this part shall—

''(1) establish a system for—

''(A) identifying, collecting information about, and evaluating medical events that occur with respect to a patient in the care of the provider of services or a practitioner employed by the provider of services, that may include—

''(i) the provision of a medically coherent description of each event so identified;

''(ii) the provision of a clear and thorough accounting of the results of the investigation of such event under the system; and

''(iii) a description of all corrective measures taken in response to the event; and

''(B) determining appropriate follow-up actions to be taken with respect to such events;

''(2) establish policies and procedures with respect to when and to whom such events are to be reported;

''(3) take appropriate follow-up action with respect to such events; and

''(4) submit to the appropriate medical event analysis entity information that contains descriptions of the medical events identified under paragraph (1)(A).

''(b) PROMOTING IDENTIFICATION, EVALUATION, AND REPORTING OF CERTAIN MEDICAL EVENTS.—

''(1) IN GENERAL.—Notwithstanding any other provision of law any information (including any data, reports, records, memoranda, analyses, statements, and other communications) developed by or on behalf of a provider of services with respect to a medical event pursuant to a system established under subsection (a) shall be privileged in accordance with section 925.

''(2) RULES OF CONSTRUCTION.—Nothing in this subsection shall be construed as prohibiting—

''(A) disclosure of a patient's medical record to the patient;

''(B) a health care oversight agency or public health authority from requiring a provider of services to transfer information to the agency or authority to the extent required by law; or

''(C) such an agency or authority from disclosing information transferred by a provider of services to the public in a form that does not identify or permit the identification of the health care provider or provider of services or patient.

''SEC. 925. CONFIDENTIALITY.

''(a) CONFIDENTIALITY AND PEER REVIEW PROTECTIONS.—Notwithstanding any other provision of law—

''(1) any information (including any data, reports, records, memoranda, analyses, statements, and other communications) developed by or on behalf of a health care provider or provider of services with respect to a medical event, that is contained in the National Patient Safety Database, collected by a medical event analysis entity, or developed by or on behalf of such an entity, or collected by a health care provider or provider or services for use under systems that are developed for safety and quality improvement purposes under this part—

''(A) shall be privileged, strictly confidential, and may not be disclosed by any other person to which such information is transferred without the authorization of the health care provider or provider of services; and

''(B) shall—

''(i) be protected from disclosure by civil, criminal, or administrative subpoena;

''(ii) not be subject to discovery or otherwise discoverable in connection with a civil, criminal, or administrative proceeding;

''(iii) not be subject to disclosure pursuant to section 552 of title 5, United States Code (the Freedom of Information Act) and any other similar Federal or State statute or regulation; and

''(iv) not be admissible as evidence in any civil, criminal, or administrative proceeding;

without regard to whether such information is held by the provider or by another person to which such information was transferred;

''(2) the transfer of any such information by a provider of services to a health care oversight agency, an expert organization, a medical event analysis entity, or a public health authority, shall not be treated as a waiver of any privilege or protection established under paragraph (1) or established under State law.

''(b) PENALTY.—It shall be unlawful for any person to disclose any information described in subsection (a) other than for the purposes provided in such paragraph, and any person violating the provisions of this section shall, upon conviction, be fined in accordance with title 18, United States Code, and imprisoned for not more than 6 months, or both.

''(c) APPLICATION OF PROVISIONS.—The protections provided under subsection (a) and the penalty provided for under subsection (b) shall apply to any information (including any data, reports, memoranda, analyses, statements, and other communications) collected or developed pursuant to research, including demonstration projects, with respect to medical error reporting supported by the Director under this part.

''SEC. 926. AUTHORIZATION OF APPROPRIATIONS.

''There is authorized to be appropriated to carry out this part, $50,000,000 for fiscal year 2001, and such sums as may be necessary for subsequent fiscal years.''.

SEC. 4. EFFECTIVE DATE.

The amendments made by section 3 shall become effective on January 1 of the calendar year that begins after the date of the enactment of this Act.

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